IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of: Joel S. Hochman, et al

Ser. No.: 10/007,393

Filed: October 26, 2001

For: SYSTEM AND METHOD FOR TRANSDUCING, SENSING OR AFFECTING VAGINAL OR BODY CONDITIONS, AND/OR STIMULATING PERINEAL MUSCULATURE AND NERVES USING 2-WAY WIRELESS COMMUNICATIONS

Examiner: Charles A. Marmor

Group: 3736

Commissioner for Patents

PO Box 1450

Alexandria VA 22313

DECLARATION TO SUPPORT THE NON-APPLICABILITY OF THE GUICE PATENT

I, Christopher J. Jayne, MD, declare as follows:

1. I am a Graduate with Honors from Buffalo School of Medicine, Buffalo New York, completed a residency in Obstetrics and Gynecology with Honors at Baylor College of Medicine, Houston Texas. I am Board Certified and a Fellow of the American College of Obstetricians and Gynecologists, and a Certified Sex Counselor by the American Association of Sex Educators Counselors and Therapists. I am the Medical Director of The Center for Women's Sexual Health at the Texas Medical Center in Houston Texas. I am a member of the Clinical Faculty at the Baylor College of Medicine in Houston Texas.
2. I am familiar with the subject matter of the above-identified application. In addition, I have carefully studied U.S. Patent Publication 2002/0010390, Guice, et al.
3. Based on my knowledge and expertise, I hereby state that one of ordinary skill in the art would not consider the Guice reference when trying to provide a system and method for transducing vaginal conditions, affecting vaginal or body conditions, and stimulating perineal musculature and nerves in humans.

4. In particular, one of ordinary skill in the art would not look to Guice, which is clearly limited to use in animals, for any teaching or suggestion with respect to how to use or configure a device that is intended to be temporarily, i.e. in a non-implanted manner, inserted into a human vagina, which are stated limitations of claim 1 of the above-identified application. As indicated, Guice is clearly limited to use in animals, which is very understandable given the significant anatomical differences between the vaginas of animals, and especially cows, and those of humans. This is supported by FDA standards and regulations and safety concerns that define implants, as will be discussed below. See also 21 CFR Part 1, which discusses FDA regulation of devices to assure their safety and effectiveness, and also 21 CFR 895 with respect to banned devices.

5. Regarding the use of the terms "non-implanted", "implant", and terms derived therefrom, these terms are all terms of the art in our field. Furthermore, with regard to definitions, limitations, etc. for these terms, the devices utilized in our field are regulated by the FDA, especially due to health and safety concerns, since they are medical devices (see, for example, 21 CFR 876.5320 regarding a non-implanted electrical continence device). Therefore, since with respect to such devices we must comply with the FDA Rules, Standards and Regulations, one of ordinary skill in the art in this field would, of course, and does, in the ordinary usage of these terms, understand these terms in a manner fully consistent with the applicable FDA definitions found in Title 21 of the Code of Federal Regulations.

6. Guice, for example in [0179], makes it clear that his device is adapted to be compressed and then expanded to keep the device in place in an ear canal or other cavity of an animal. Guice even suggests adhesive. A tool, such as pliers, is needed to be able to install and remove the device from the animal. One of ordinary skill in the art would not consider that such a device "is adapted to be inserted into the human vagina", and in fact would consider the Guice device to be an implant. In contrast, the device of the above-identified patent application for Hochman is to be "self-applied" or "self-inserting" by a human subject, which to one of ordinary skill in the art is clearly understood to mean without the use of a tool, such as the pliers required by Guice.

7. In the medical and veterinary fields, the device of the above-identified application of Hochman is not an implant, i.e. has a non-implanted probe. In contrast, the device of Guice would be considered by one of ordinary skill in the art to be an implant, and this is also true under FDA standards (see for example 21 CFR 812.3(d).) Thus, the device of Guice is in no way comparable to the device of the above-identified application, which is temporarily insertable, or self-applicable, by a human subject. Guice itself stresses that his device is a true implant, i.e. is to be implanted, or is an implant, which one of ordinary skill in the art clearly understands to be the opposite of "non-implanted", since if it is to be implanted it cannot be a non-implanted device. The reason for the Guice device being an implant is in large part due to the aforementioned differences in the anatomy of humans and animals, which requires that the device of Guice, in order to be effective, i.e. retained, must be implanted in the animal being monitored; if it were not implanted, it would be expelled upon urination. Furthermore, as mentioned above, also pursuant to FDA standards and definitions, the Guice device is an implant whereas the device of the above-identified application is not, as confirmed by the FDA device approval letter issued to Athena.

8. In conclusion, the Guice device is entirely unsuitable for human vaginal use, and one of ordinary skill in the art would not consider the Guice reference for any teaching or suggestion with regard to the configuration of a device that is to be temporarily inserted, i.e. non-implanted, into the human vagina, for example because one of ordinary skill in the art simply would not consider an implantable animal device when trying to come up with a device that is adapted to be inserted into a human vagina. I respectfully submit that to assert that a device made for a cow's vagina, or ear or any other cavity, would be capable of being inserted into a human vagina is simply not a reasonable interpretation to one of ordinary skill in this art.

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful, false statements may jeopardize the validity of

this application, the patent which issues thereon, or any patent to which this verified statement is directed.

3/22/06

Christopher J. Jayne, MD, FACOG
AASECT Certified Sex Counselor
Medical Director, The Center for Women's Sexual Health

Date

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DECLARATION TO SUPPORT THE NON-APPLICABILITY OF THE GUICE PATENT

I, Kurt R. Wharton MD, declare as follows:

1. I received an A.B. Degree in Physiology and Anatomy from the University of California at Berkeley in 1980. I received my Medical Degree from Boston University School of Medicine in 1984. After completing an Internship in Obstetrics and Gynecology at Mount Zion Hospital and Medical Center in 1985, I was a Resident in the Department of Obstetrics, Gynecology and Reproductive Sciences at the University of California, San Francisco from 1985 through 1987.I served as Administrative Chief Resident during the academic year ending in 1988. I am currently Chairman, Department of Obstetrics and Gynecology at Alta Bates Summit Hospital in Berkeley, California. Additionally, I am the Site Director for Resident Education and I hold the Academic position of Associate Clinical Professor in the Department of Obstetrics, Gynecology and Reproductive Sciences at the University of California, San Francisco. I am a Fellow of the American College of Obstetrics and Gynecology and I am Board Certified by the American Board of Obstetrics and Gynecology.

2. I am familiar with the subject matter of the above-identified application. Additionally, I have reviewed the U.S. Patent Publication 2002/0010390, Guice, et al.

   Based upon my training and professional expertise in Human Physiology, Obstetrics, Gynecology and Women's Health, I can state that no consideration would be given to the Guice Patent by individuals attempting to develop biomedical systems intended to transduce vaginal conditions, affect vaginal or body conditions, or stimulate perineal neuromuscular tissues in humans.

3. By recognized clinical medical standards, the Guice Patent is a Patent for an implant. The Patent clearly identifies telesensor implant units intended for implantation in the ear, vagina, rectum, throat, nostril or subcutaneous tissues of an animal. The telesensors may also be implanted percutaneously. To be explicit, implants are devices surgically placed within or through tissues. Examples of human implants include the Norplant Contraceptive Devices and Cardiac Pacemakers. Human implants require surgical placement and removal. Paragraph 0164 of the Guice Patent states "the telesensor implant, which may be exposed to animal tissue or fluids, should be biocompatible, and in many cases, should promote the ingrowth of tissue to help anchor the telesensor implant in the desired implant location." Obviously, such a device is unacceptable and inappropriate for insertion in the human vagina.

4. Examples of intravaginal medical devices that are not implants, i.e. are non-implanted devices, include contraceptive diaphragms, pessaries used to treat genital organ prolapse, and medical delivery systems such as the contraceptive NuvaRing and the estrogen releasing Estring. Such devices are placed into the vagina by the patient or healthcare provider and easily removed by the patient or healthcare provider. No surgery, tools or adhesives are required. The Patent requested by Athena provides a non-implanted or temporarily insertable medical device, which is in no way comparable to the Guice implant device.

5. In summary, the Guice implant device is in no way appropriate or acceptable for insertion in the human vagina. Individuals of ordinary skill in the art developing medical devices for temporary placement, i.e. application or insertion, within the human vagina would not consider the Guice reference.

6. I hereby declare that all statements made herein are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so make are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful, false statements may jeopardize the validity of this application, the patent which issues thereon, or any patent to which this verified statement is directed.

Kurt R. Wharton MD

3/01/06
Date